

REMARKS

Claims 15-20, 23-32 and 42-44 remain pending in this application. Claims 1-14, 21, 22 and 33-40 have been cancelled, without prejudice.

Claims 15-21, 23-32 and 42-44 stand rejected under 35 U.S.C. § 102 as being anticipated by Ersek (U.S. Patent No. 3,657,744). Applicant traverses the rejection. Applicants submit that, as amended, independent claim 15 is not anticipated by Ersek. Claim 15 requires that "the at least one ring [be] attached to the outside surface at *only the proximal end of the sleeve*." Ersek describes attaching a valve to a stent-like, tubular sleeve 16 (Fig. 8), or a sleeve 16A with holes (Fig. 2), or a sleeve 16B with rectangular openings (Fig. 3), or a fixation device 16C with two narrow mesh rings (Fig. 4). In each case, the valve is affixed either to both a lower part of the sleeve and an upper part of the sleeve, in the devices shown in Figs. 2, 3 and 8, or to a lower mesh ring and an upper mesh ring, in the device shown in Fig. 4. See, for example sutures 47 and 49 in Figure 8, and the specification describing Figs. 2-4 and 8 at column 3, line 36 through column 4, line 31.

Claims 15-21, 23-32 and 42-44 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Peale (U.S. Patent No. 15,192) or Rygg (U.S. Patent No. 4,218,782) in view of Sakura (U.S. Patent No. 4,214,587) or Ersek. As described in previous responses, Applicant submits that a prima facie obviousness case has not been made with respect to the proposed combinations. Peale discloses valves for *syringes, pumps and other instruments* that are intended to imitate as nearly as may be, the valves of the arterial, and other portions, of the human organization". Peale col 1:10-13. Peale does not describe a valve for human implantation, but instead a valve that mimics a human valve for use with a machine. In contrast, while Rygg describes a valve for human implantation, it specifically *teaches away* from combining the valve with a stent like that described in Ersek or an anastomosis-type device described in Sakura. See column 2, lines 28 through 52, where drawbacks of attaching a valve material to stents are discussed and column 3, line 20, where the object of the Rygg invention is: "to provide a flexible non-stented heart valve prosthesis which has the advantages known from the use of biological membranes without being encumbered with the known drawbacks." Applicant thus submits that

the combination of a valve as shown in Peale or Rygg with an attachment device shown in Sakura or Ersek fail to satisfy a prima facie obviousness showing as there is no suggestion for the combination.

In an event, Applicant submits that the invention described in amended claim 15 is not shown or described in any of the references of record. As is described above, claim 15 is amended to claim a valve for implantation at a desired location within a mammal that includes a flexible sleeve having a proximal end, a distal end and an outside surface; at least one cusp configured to permit blood flow through the at least one cusp in a single direction; at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted; and at least one fastener extending in a direction radially outward with respect to the sleeve. None of the cited references describes or suggests an embodiment that has at least one ring attached to the outside surface of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted. As a result, Applicant submits that none of the cited references can be combined to show all of the elements of the claimed element, and requests that the Examiner indicate that claims 15-20, 23-32 and 42-44 are allowable.

Applicants grant the PTO permission to charge the deposit account no. 10-0750/BST/HRT0287 for any fees or charges related to this application. Applicant respectfully requests the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

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Dated: August 1, 2006